glycerin supply in the cigarette rod, which vaporizes and extracts nicotine, but is intended to produce very little of the normal constituents of tar, as it passes through the rod to the smoker's mouth. The final Eclipse smoke vapor is 85% water, glycerol, and nicotine (versus 25% in standard cigarette smoke) and only 15% tar (versus 75% in standard smoke).[490] Thus, Eclipse is intended to deliver nicotine at levels similar to conventional ultra-low-tar cigarettes, but much lower levels of tar.[491]

In its comments, RJR asserts that "Premier *was* a cigarette" because it provided the smoker with "smoking taste and pleasure."[492] Likewise, RJR asserts that "Eclipse is a cigarette."[493] But the major similarity in the vapor from Premier and Eclipse and the smoke from a conventional cigarette is the nicotine delivery. The implication of RJR's work on Premier and Eclipse is that nicotine delivery is the defining characteristic of a cigarette. As RJR informed FDA officials during the launch of Premier, "without nicotine, you don't have a cigarette."[494] Premier and Eclipse are thus evidence that conventional cigarettes are, in effect, simply nicotine delivery systems.

iv. RJR's Legal Briefs. Before the Agency, RJR argues that nicotine is not addictive and that the Agency should not believe the widespread "allegations" to the

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[490] Hilts P, Little smoke, but still lots of nicotine, *New York Times*, Nov. 27, 1994. See AR (Vol. 34 Ref. 568).

[491] Feder BJ, Ready to test new cigarette, maker fears tough rules, *New York Times*, Apr. 8, 1996. *See* AR (Vol. 700 Ref. 225).

[492] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 34-35 (emphasis added). *See* AR (Vol. 519 Ref. 103).

[493] R.J. Reynolds Tobacco Co., Comment (Apr. 19, 1996). *See* AR (Vol. 700 Ref. 225).

[494] Department of Health and Human Services, Memorandum of meeting, *RJR's "Smokeless" Cigarette* (Oct. 23, 1987), at 3. *See* AR (Vol. 34 Ref. 558-2).

contrary. However, RJR has taken exactly the opposite position in court cases. There RJR argues that the risk of becoming addicted to cigarettes is so foreseeable to consumers that consumers must be held to have assumed the risk. For instance, in one case RJR argued that consumers should not be allowed to sue cigarette manufacturers on the grounds that they become addicted, because they should have foreseen this risk:

> There can be no serious suggestion that ordinary consumers do not expect to find nicotine in cigarettes, or that ordinary consumers have not long been well aware that it may be very difficult to stop smoking. *The common knowledge of the alleged habituating or "addicting" properties of cigarettes has resulted in almost casual references to these properties in decisions from around the country throughout this century.*[495]

RJR asserts that this statement does not acknowledge addiction because RJR is merely stating that "allegations" concerning the addictive properties of cigarettes are well known. However, RJR's position in the litigation and its position before the Agency are in fundamental conflict. RJR cannot consistently deny its awareness of nicotine's addictive properties while at the same time claiming that its consumers should be deemed to have an awareness of these properties. RJR's recognition of "the common knowledge of the alleged habituating or 'addicting' properties of cigarettes" is thus further evidence of RJR's awareness of the addictive and other pharmacological effects of cigarettes.

In sum, the internal RJR memoranda in the administrative record, RJR's published research into nicotine pharmacology, RJR's development of alternative tobacco products that function as nicotine delivery devices, and even RJR's litigation briefs all point to the

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[495] Appellees brief in reply to appellants' opposition to petition for transfer, *Rogers v. R.J. Reynolds et al.* (Sup. Ct. Ind.) (No. 49A02-8904 CV 164) (1990), at 7-8 (citation omitted) (emphasis added). *See* AR (Vol. 21 Ref. 229).

conclusion that RJR knows that its cigarettes will have pharmacological effects, that consumers will purchase its products to obtain these effects, and that, in essence, its cigarettes function as nicotine delivery devices. This is persuasive evidence that RJR intends its product to affect the structure and function of the body.

c. The Statements and Research of Brown & Williamson

The administrative record includes a large array of documents from the Brown & Williamson Tobacco Corporation, the third largest cigarette manufacturer in the United States, and its corporate parent, BAT Industries PLC, formerly British-American Tobacco Company (BATCO). These documents show that Brown & Williamson and BATCO have conducted extensive research on nicotine's pharmacological effects and that for over 30 years senior researchers and officials at Brown & Williamson and BATCO have considered nicotine to be "addictive;"[496] "an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses"[497] and the reason "why people inhale smoke."[498]

The documents from Brown & Williamson and BATCO in the administrative record include many unpublished reports from company research, internal memoranda, and reports from conferences of company scientists. These documents are summarized in the following chronology, which illustrates that the companies have long regarded

[496] *See, e.g.*, Yeaman A (Brown & Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4. *See* AR (Vol. 21 Ref. 221).

[497] BATCO Group R&D, *Method for Nicotine and Cotinine in Blood and Urine* (May 21, 1980), at 2. *See* AR (Vol. 23 Ref. 300-1).

[498] Greig CC (BATCO), *Short Lived Species in Smoke* (Jan. 26, 1984), attached to letter from Ayres CI (BATCO) to Kohnhorst EE (Brown & Williamson) (Feb. 9, 1984), at 10. *See* AR (Vol. 34 Ref. 584).

themselves as "in a nicotine rather than a tobacco industry."[499] Although the statements of company scientists and officials seem to become somewhat more guarded with time, the documents show a consistent recognition of nicotine's pharmacological effects and uses, including its role in causing and sustaining addiction.

i. Statements and Research in the 1960's. In the 1960's, senior officials at BATCO and Brown & Williamson and their senior researchers candidly discussed nicotine's "addictive" and "drug" effects in internal meetings. In a 1962 conference of BATCO researchers, for instance, Charles Ellis, the science advisor to the BATCO board, acknowledged that "*smoking is a habit of addiction.*"[500] He described the role of nicotine in cigarettes as follows:

> *It is my conviction that nicotine is a very remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquillising effect. . . . Nicotine is not only a very fine drug, but the techniques of administration by smoking has [sic] considerable psychological advantages and a built-in control against excessive absorption.* It is almost impossible to take an overdose of nicotine in the way it is only too easy to do with sleeping pills. [501]

Charles Ellis recommended that BATCO conduct research "to investigate whether cigarette smoke produces effects on the central nervous system characteristic of tranquilising or stimulating drugs and, if so, to see if such activity is due solely to nicotine."[502] The Battelle Memorial Institute in Geneva, Switzerland, conducted this

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[499] Johnson RR (BATCO), *Comments on Nicotine* (Jun. 30, 1963), at 10-11. *See* AR (Vol. 21 Ref. 242).

[500] Ellis C (BATCO), *The smoking and health problem,* in *Smoking and Health–Policy on Research,* Research Conference, Southampton, England (1962), at 4 (emphasis added). *See* AR (Vol. 21 Ref. 220).

[501] *Id.* at 15-16 (emphasis added).

[502] *Id.* at 16.

research for BATCO, producing a series of reports in 1963 called "HIPPO I," "HIPPO II," "The Fate of Nicotine in the Body," and "A Tentative Hypothesis on Nicotine Addiction."

These reports substantiated and explained nicotine's drug-like and addictive effects. "HIPPO II," for instance, suggested that "*the key to the explanation of both phenomena of tolerance and of addiction*" to nicotine could be found through "[a] quantitative investigation of the relations with time of nicotine—and of some possible brain mediators—on adreno-corticotrophic activity."[503] The report further stated that "the so-called 'beneficial effects' of nicotine are of two kinds: 1. Enhancing effect on the pituitary-adrenal response to stress; 2. Regulation of body weight."[504]

Similarly, "The Fate of Nicotine in the Body" found that nicotine "*appears to be intimately connected with the phenomena of tobacco habituation (tolerance) and/or addiction.*"[505] It also reported "[t]here is increasing evidence that *nicotine is the key factor in controlling, through the central nervous system, a number of beneficial effects of tobacco smoke*, including its action in the presence of stress situations."[506]

"A Tentative Hypothesis on Nicotine Addiction" stated that "the hypothalomo-pituitary stimulation of nicotine is *the beneficial mechanism which makes people smoke,*

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[503] Haselbach C, Libert O, *Final Report on Project HIPPO II* (Mar. 1963), at 4 (emphasis added). *See* AR (Vol. 64 Ref. 321).

[504] *Id.* at 2.

[505] Geissbuhler H, Haselbach C, *The Fate of Nicotine in the Body* (May 1963), at 1 (emphasis added). *See* AR (Vol. 21 Ref. 243).

[506] *Id.* at 1 (emphasis added).

in other words, nicotine helps people to cope with stress."[507] The report then suggested that nicotine addiction could be explained as follows:

> If nicotine intake, however, is prohibited to chronic smokers, the corticotropin-releasing ability of the hypothalmus is greatly reduced, so that these individuals are left with an unbalanced endocrine system. *A body left in this unbalanced status craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine.*[508]

The Battelle reports were distributed to the top officials at Brown & Williamson and other tobacco companies. Charles Ellis sent copies of the Battelle reports to the president of Brown & Williamson, William S. Cutchins. Brown & Williamson in turn sent the Project Hippo reports to RJR.[509]

In July 1963, Brown & Williamson's general counsel, Addison Yeaman, wrote an internal memorandum entitled "Implications of Battelle Hippo I and II and the Griffith Filter." He stated that "*nicotine is addictive*" and that "*[w]e are, then, in the business of selling nicotine, an addictive drug . . .* "[510]

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[507] Haselbach C, Libert O, *A Tentative Hypothesis on Nicotine Addiction* (May 30, 1963), at 1 (emphasis added). *See* AR (Vol. 20 Ref. 197).

[508] *Id.* at 2 (emphasis added).

[509] Note to Cutchins WS (Brown & Williamson) (Jun. 19, 1963). *See* AR (Vol. 14, Ref. 165-4).

Letter from Ellis C (BATCO) to Yeaman AY (Brown & Williamson) (Jun. 28, 1963). *See* AR (Vol. 14 Ref. 165-2).

Letter from Yeaman AY (Brown & Williamson) to Jacob EJ (R.J. Reynolds Co.) (Aug. 5, 1963). *See* AR (Vol. 14 Ref. 165-3).

[510] Yeaman AY (Brown & Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4 (emphasis added). *See* AR (Vol. 21 Ref. 221).

These views were frequently reiterated. In June of 1967, Charles Ellis stated, "*we are in a nicotine rather than a tobacco industry.*"[511] Several months later, at an October 1967 meeting, BATCO researchers agreed that "*[s]moking is an addictive habit attributable to nicotine.*"[512]

In 1968, Sidney J. Green, who was a member of BATCO's board as well as the company's director of research, acknowledged that one "recognisable type" of smoking behavior is "*addictive*" smoking. He added, "it seems a good assumption that *nicotine plays a predominant role for many smokers. . . . [A] good part of the tobacco industry is concerned with the administration of nicotine to consumers.*"[513]

Similarly, at another BATCO research conference in 1968, the researchers agreed that nicotine has "*pre-eminent importance*" and that "the pharmacology of nicotine should continue to be kept under review."[514]

A year later, at a 1969 meeting of BATCO researchers, BATCO scientist D. J. Wood stated:

> The presence of nicotine is the reason why the tobacco plant was singled out from all other plants for consumption in this rather unusual way.
>
> *Nicotine has well documented pharmacological action. It is claimed to have a dual effect, acting both as a stimulant and a tranquilliser. It is believed to be responsible for the "satisfaction"*

[511] Johnson RR (BATCO), *Comments on Nicotine* (Jun. 30, 1963), at 10 (emphasis added). *See* AR (Vol. 21 Ref. 242).

[512] Minutes of BATCO Group R&D Conference at Montreal, Canada (Oct. 24, 1967), at 2 (emphasis added). *See* AR (Vol. 21 Ref. 206-4). FDA notes that the version of this document made public by Congress contains a handwritten edit changing "an addictive habit" to "a habit."

[513] Green SJ (BATCO), *BAT Group Research* (Sep. 4, 1968), at 1-2 (emphasis added). *See* AR (Vol. 15 Ref. 192).

[514] Minutes of BATCO Research Conference at Hilton Head, SC (Sep. 24-30, 1968), at 3 (emphasis added). *See* AR (Vol. 31 Ref. 525-1).

of smoking, using this term in the physiological rather than the psychological sense.[515]

And at another 1969 conference of BATCO scientists, the following conclusion was reached: "*[t]he Conference agreed that all the evidence continues to demonstrate the importance of nicotine to the smoker. . . .*"[516]

Numerous other similar statements were made by Brown & Williamson and BATCO researchers and officials in the 1960's. They are described in the Jurisdictional Analysis. *See* 60 FR 41584–41586. Collectively, these statements show that even as early as the 1960's, Brown & Williamson and BATCO officials knew the addictive and other pharmacological effects of nicotine, knew that consumers smoked cigarettes for these effects, and viewed themselves as in the drug delivery business.

ii. Statements and Research in the 1970's and 1980's. Throughout the 1970's and 1980's, Brown & Williamson and BATCO officials continued to emphasize the importance of nicotine in cigarettes. At a 1970 conference of BATCO researchers, for instance, the researchers postulated that "*[n]icotine is important, and there is probably a minimum level necessary for consumer acceptance in any given market.*"[517]

In 1972, S.J. Green, the BATCO board member and research director, stated that "*[t]he tobacco smoking habit is reinforced or dependent upon the psycho-*

[515] Wood DJ (BATCO), *Aspects of the R&DE Function*, Notes for a talk given by Wood DJ at Chelwood, Sep. 1969 (Jul. 20, 1970), at 7 (emphasis added). *See* AR (Vol. 22 Ref. 287).

[516] Minutes of BATCO Research Conference at Kronberg (Jun. 2-6, 1969), at 7 (emphasis added). *See* AR (Vol. 14 Ref. 172-4).

[517] Summary and conclusions of BAT Group Research Conference at St. Adele, Quebec (Nov. 9-13, 1970), at 1 (emphasis added). *See* AR (Vol. 23 Ref. 294).

pharmacological effects mainly of nicotine."[518] Similarly, a 1972 BATCO research report observed:

> It has been suggested that *a considerable proportion of smokers depend on the pharmacological action of nicotine for their motivation to continue smoking.*
>
> If this view is correct, *the present scale of the tobacco industry is largely dependent on the intensity and nature of the pharmacological action of nicotine.*[519]

These statements demonstrate an awareness that nicotine has "reinforcing" effects, one of the hallmarks of an addictive substance, and that the tobacco industry is built upon these effects.

At a 1974 BATCO conference, company scientists reported that BATCO research had found that consumers appear to smoke to fulfill their "nicotine requirements," stating that "the Kippa study suggests that whatever the characteristics of cigarettes as determined by smoking machines, *the smoker adjusts his pattern to deliver his own nicotine requirements (about 0.8 mg per cigarette).*"[520]

At a 1976 BATCO conference on smoking behavior, the researchers again stated that nicotine has reinforcing effects on smokers, observing that nicotine is "*known to be pharmacologically active in the brain*" and is "*considered to be the reinforcing factor in the smoking habit for at least 80% of smokers.*"[521]

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[518] Green SJ (BATCO), *The Association of Smoking and Disease* (Jul. 26, 1972), at 1 (emphasis added). *See* AR (Vol. 15 Ref. 193).

[519] Kilburn KD, Underwood JG (BATCO), *Preparation and Properties of Nicotine Analogues* (Nov. 9, 1972), at 2 (citations omitted) (emphasis added). *See* AR (Vol. 31 Ref. 524-1).

[520] Notes on BATCO Group R&D Conference at Duck Key, FL (Jan. 12-18, 1974), at 2 (emphasis added). *See* AR (Vol. 25 Ref. 327).

[521] Minutes of BATCO Group R&D Conference on Smoking Behaviour at Southampton, England (Oct. 11-12, 1976), at BW-W2-02145, BW-W2-02152–BW-W2-02153 (emphasis added). *See* AR (Vol. 14 Ref. 180).

At a 1977 conference, nicotine was once more the "focal point." A Brown & Williamson summary of the conference stated that "[i]n many cases, psychological and physiological changes observed in subjects . . . were shown to be due to nicotine" and "[m]ost researchers conclude that *the nicotine effect is biphasic and dosage dependent; small doses stimulate and large doses depress.*"[522]

A year later, BATCO board member and chief researcher S.J. Green explicitly acknowledged that nicotine is addictive. Specifically, he wrote "*[t]he strong addiction to cigarette[s] removes freedom of choice from many individuals.*"[523]

A 1980 BATCO research report stated that "*[n]icotine is an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses in vivo.*"[524]

A 1981 report on the pharmacology of nicotine by the Tobacco Advisory Council, which represents U.K. tobacco manufacturers including BATCO, stated that "*nicotine is regarded as the most pharmacologically-active compound in tobacco smoke*" and concluded that "*[i]n a nutshell, our approach has been to regard nicotine as a 'drug.'*"[525]

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[522] Trip report of BATCO International Smoking Behavior Conference at Chelwood Vachery, England (Jan. 6, 1978), at 1-2 (emphasis added). *See* AR (Vol. 178 Ref. 2075).

[523] Notes of Green SJ (1978) (emphasis added). *See* AR (Vol. 528 Ref. 97, appendix 18).

[524] BATCO Group R&D, *Method for Nicotine and Cotinine in Blood and Urine* (May 21, 1980), at 2 (emphasis added). *See* AR (Vol. 23, Ref. 300-1).

[525] Cohen AJ, Roe FJC (Tobacco Advisory Council), *Monograph on the Pharmacology and Toxicology of Nicotine* (1981), at 1, 17 (emphasis added). *See* AR (Vol. 14 Ref 184).